

## **REMARKS/ARGUMENTS**

### ***Claim Objections - 35 U.S.C. §112***

1. The Examiner indicated that the lettering of the steps in claim 5 suggest that there are further steps to be carried out after completing the steps disclosed in claim 1. The specification is clear that this is not the case and ergo, the Applicant has removed the lettering of the steps in claim 5.
2. The Examiner objected to the limitation “said excipients and/or adjuvants in the weight proportions defined above” in claim 5. Applicant has clarified this by removing the “said” and “in the weight proportions defined above” portions of claim 5.
3. The Examiner objected to the limitation of “said at least one fat...” in claim 5. Applicant has amended claim 5 to remove such language.
4. The Examiner objected to the limitation of “at least one fat” in claim 10. Applicant has amended said language to read “said fatty acid.”
5. The Examiner objected to the limitation of “excipients and or adjuvants” in claim 10 as not having antecedent basis. Applicant’s amendment to claim 5 provides the necessary antecedent basis. Applicant notes that it has corrected the spelling of excipients in claim 10.
6. The Examiner objected to the broad range or limitations of claims 5 and 7. This situation also exists in claim 9 as filed. Applicant has amended claims 5, 7, and 9 to render said claims definite, in the process moving the narrower statement of the ranges to new claims 14-17.
7. The new claims 14-15 require the amendment to claim 6.
8. Such changes add no new matter.

### ***Claim Rejections - 35 USC §103***

9. The Examiner rejected claims 1-13 under §103(a) as being unpatentable (obvious) in view of Palepu et al.
10. “To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make

the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 706.02(j).

11. The law regarding obviousness is clear--any modification of the prior art must be suggested or motivated by the prior art:

'Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.' [citation omitted] Although couched in terms of combined teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

*In re Fitch*, 972 F.2d 1260, 23 USPQ2d 1780, 1783-4 (Fed.Cir. 1992), (in part quoting from *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

12. There is no motivation whatsoever provided by Palepu et al. to provide for the claimed temperature ranges, nor the replacement of the thermal infusion process disclosed by Palepu et al. with the instant melt granulation process simply by experimentation.

13. It is also submitted that the mere fact that one may argue that the prior art is capable of being modified to achieve a claimed structure does not by itself make the claimed structure obvious--there must be a motivation provided by the prior art, and that motivation is totally lacking in the reference.

The examiner finds the claimed shape would have been obvious urging that (our emphasis) "it is obvious for one skilled in the art to form each hook base of any desired shape \*\*\* since *this is within the capabilities of such a person*." Thus, the examiner equates that which is within the capabilities of one skilled in the art with obviousness. Such is not the law. There is nothing in the statutes or case law which makes "that which is within the capabilities of one skilled in the art" synonymous with obviousness.

The examiner provides no reason why, absent the instant disclosure, one of ordinary skill in the art would be motivated to change the shape of the coil hooks of Hancock or the German patent and we can conceive of no reason.

*Ex parte Gerlach and Woerner*, 212 USPQ 471 (PTO Bd. App. 1980) (emphasis in original).

14. Palepu et al. is complete and functional without the need for modification. As such, there is need to modify Palepu et al. by replacing the thermal infusion process with the instant melt granulation process including the claimed temperature ranges. The Examiner has further provided no reason why one of ordinary skill in the art would be motivated to make such a change. Absent the need for modification to provide functionality, the Palepu et al. reference could never lead one to make modifications to meet the present invention's claims.

15. The initial burden is on the Examiner to provide some **suggestion** of the desirability of doing what the inventor has done.

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly **suggest** the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."

*Ex Parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. and Inter. 1985). MPEP § 706.02(j) (emphasis added).

16. This suggestion for modification must be **motivating**.

"The prior art must provide one of ordinary skill in the art the **motivation** to make the proposed molecular modifications needed to arrive at the claimed compound."

*In re Jones*, 21 USPQ2d 1941, 1944 (Fed. Cir. 1992) (emphasis added).

17. Even if the prior art may be modified as suggested by the Examiner, the modification is not obvious unless the prior art suggest the **desirability** for the modification. *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992) ("mere fact that prior art may be modified to reflect features of claimed invention does not make the modification, and hence, the claimed invention, obvious unless the desirability of such a modification is suggested by prior art). Citing *In re Gordon*, 733 F.2d at 902, 221 USPQ at 1127.

18. Moreover, the motivating suggestion must also be **explicit**. An invention cannot be found obvious unless there is "some **explicit** teaching or suggestion in art to motivate one of even ordinary skill to combine such elements so as to create the same invention." *Winner International Royalty Corp. v. Wang*, 48 USPQ2d 1139, 1140 (D.C.D.C. 1998).

19. The Examiner's suggested change (replacing the thermal infusion process of Palepu et al. with the instant melt granulation process simply by routine experimentation) is not suggested, motivated, desirable or explicit.

20. Palepu et al. clearly states that melt granulation processes are known in the art but spends great length in discussing the disadvantages and problems associated to the use of such a technology for manufacturing retarded release formulations (see col. 1, line 60 to col. 2, line 8). Consequently, one skilled in the art would have never looked at the thermal infusion as a possible alternative in order to obtain a retarded release formulation. It is clear that Palepu et al. expressly teaches away from the present invention. Because Palepu et al. teaches away, there can be no motivation.

21. The present invention is non-obvious.

***Conclusion***

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below. Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 15<sup>th</sup> day of July 2003.

Very respectfully,



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**CERTIFICATE OF MAILING**

I HEREBY CERTIFY that this correspondence is being deposited with the United States Postal Service on the below date as first class mail in an envelope addressed to:

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DATE: July 15<sup>th</sup>, 2003

Shannon M. Wilson

